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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,293	03/29/2004	Mark James Batchelor	CELL-0281	2277

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
06/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,293

Applicant(s)

BATCHELOR ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-8 and 11 are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-8 and 11 are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/596,952.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on March 26, 2007.

Claims 1-2, 6-8 and 11 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation: "at least one of $-R^4$ and $Alk(R^4)_m$ is a $X^{1a}(Alk^a)_pNR^{7a}R^{7b}$, $X^{1a}(Alk^a)_pNHet^1$, or $X^{1a}(Alk^a)_pNAr^{2a}$ " in lines 2-7. There is insufficient antecedent basis for this limitation in claims 6 or 7 on which claim 8 is dependent. These terms are not present in any of the preceding claims.

Applicant submits that 'claim 6 recites that R^4 can be a substituted amino group and when read in light of the teachings in the present application, antecedent basis is provided for the terms $X^{1a}(Alk^a)_pNR^{7a}R^{7b}$ and $X^{1a}(Alk^a)_pNHet^1$ '. This is not found to be persuasive.

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The substituents represented by the terms recited in claim 8 appear to be broader than those of claim 6. The instant claim defines X^{1a} to be 'a direct bond or a linker group selected from $-C(O)-$, $-C(S)-$, ..., and $-N(R^7)SO_2N(R^7)-$ '. For example, if X^{1a} is $-N(R^7)C(O)O-$, a representative substituent $-R^4$ or $-Alk(R^4)_m$ according to claim 8 would be $-N(R^7)C(O)O-(Alk^a)_p-NR^{7a}R^{7b}$, wherein R^7 is hydrogen or C_{1-6} alkyl. However, claim 6 does not provide a substituent that is equivalent or a group that encompasses the substituent intended by the various groups in claim 8. Further, see many of the terms recited under R^4 in claim 6 have $-NH-$ group (see e.g., $-NHCOR^5$, $-NHCONH_2$, etc.) and the terms in claim 8 contain $-N(R^7)-$ wherein R^7 is H or alkyl, which is obviously of a broader scope than that provided in claim 6 on which claim 8 is dependent.

(A representative example of the substituent based on the groups provided in claim 8 is discussed above to show that the substituents recited in claim 8 lack antecedent basis in claim 6).

The following rejections are under new grounds:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 6-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that “undue experimentation” would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The specification fails to enable the preparation of the entire scope of the claimed compounds. The process schemes discussed in the specification at pages 24-33 provide the essential starting materials to prepare the claimed compounds of formula (1) as compounds (2), (3), (4), (5), (6), and (7). However, there is no disclosure of the sources of starting materials needed to prepare for the instantly claimed compounds of formula (1) wherein R^2 is $-X^1-R^3$ wherein X^1 is a linker group selected from $-C(O)-$, $-C(S)-$, $-N(R^7)SO_2N(R^7)-$. All the examples in the specification are drawn to compounds wherein R^2 is $-X^1-R^3$ wherein X^1 is a direct bond. The specification does not provide guidance of the starting materials required to prepare the compounds wherein X^1 is a linker group as provided in the claims. The specification does not provide any examples of the compounds wherein the pyrimidine and the R^3 substituent are separated by a linker group X^1 as defined in the claims.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed

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compounds and therefore practice the invention. The starting material sources necessary to obtain the instant compounds must have been available as of the filing date in order to provide an enabling disclosure. See *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); *Ex parte Moersch*, 104 USPQ 122 (POBA 1954). Applicants should show that the sources of these starting materials was common knowledge or readily available at the time of filing.

Note

Applicant's attention is directed to U.S. Patent No. **6,908,920** which while is not a competent reference against the instantly claimed invention, claims subject matter that is substantially similar to that claimed herein. Particularly, the instant claims include a compound of formula (1) wherein R^2 can be $-X^1-R^3$ wherein X^1 is $-N(C_{1-6} \text{ alkyl})-$, etc. Unless applicants can demonstrate that the instant claims are patentably distinct from the claims in this US patent, the only way to overcome these patents is by way of interference proceedings or removal of the conflicting subject matter. See MPEP § 2306.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

Deepak Rao
Primary Examiner
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June 6, 2007